VIA FACSIMILE SEPTEMBER 26, 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Shi et al.	Docket No.: PT050P1
Application No.: 09/935,703	Confirmation No.: 9669
Filed: August 24, 2001	Art Unit: 1652
For: Human Protein Tyrosine Phosphatase Proteins and Genes Encoding The Same	Examiner: D. Ramirez

RESPONSE UNDER 37 C.F.R. §1.111

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed June 26, 2003 (Paper No. 8), please consider the following remarks. Applicants submit concurrently herewith: (a) a Fee Transmittal Sheet with appropriate fee (in dupl.); and (b) a Certificate of Transmission Under 37 C.F.R. § 1.8.

Claims 23-42 are pending.

I. Rejection of the Claims under 35 U.S.C. §§ 101 and 112, First Paragraph

The Examiner has rejected claims 23-42 under 35 U.S.C. § 101 because the invention is allegedly not supported by either a specific and substantial asserted utility or a well established utility. (*See* Paper No. 8, pages 4-8.) In particular, the Examiner contends that "[w]hile Applicant's assertion in regard to function may be correct, the asserted function for the polynucleotide of SEQ ID NO:2 and the polypeptide of SEQ ID NO:7 is based solely upon sequence alignment analysis and the specification does not provide any empirical evidence that the polypeptide of SEQ ID NO:7 is a tyrosine phosphatase." The Examiner has further rejected claims 23-42 under 35 U.S.C. § 112, first paragraph, because one skilled in the art would allegedly not know how to use the claimed invention, based on the supposed lack of either a specific and substantial asserted utility or a well-understood utility.

Applicants respectfully disagree and traverse these rejections.

A rejection under 35 U.S.C. § 101 is improper when a person of ordinary skill in the art would find credible disclosed features or characteristics of the invention, or statements made by

the applicant in the written description of the invention. *See* M.P.E.P. §§ 2107.01(II) – (III) (7th Ed. Rev. 1, Feb. 2000). In addition, an applicant need only make *one* credible assertion of utility for the claimed invention to satisfy 35 U.S.C. § 101. *See, e.g., Raytheon v. Roper,* 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983), *cert. denied,* 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. § 101 is clearly shown."); *see also* M.P.E.P. § 2107.01 at 2100-29; Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (January 5, 2001). Finding a lack of utility is also improper if a person of ordinary skill in the art would know of a use for the claimed invention at the time the application was filed. *See* M.P.E.P. § 2107.01(II)(B); Utility Examination Guidelines at 1098.

Moreover, the Examiner must establish why it is more likely than not that one of ordinary skill in the art would doubt (*i.e.*, "question") the truth of the statement of utility. *See* M.P.E.P. § 2107.01(II)(A); Utility Examination Guidelines at 1098-99. Thus, the Examiner must provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. *See id.* The Examiner must also present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the applicants' assertion of utility. *See id.*; *see also In re Brana,* 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995). For the reasons set forth below, Applicants respectfully assert that the Examiner has not met the required burden.

Applicants point out that the Utility Examination Guidelines require an evaluation of the utilities taught in the closest prior art. *See* Utility Examination Guidelines at 1098. In the instant case, while the Examiner addresses the homology of the claimed polynucleotides to the mouse tyrosine phosphatase, the Examiner contends that "in view of the extremely low sequence identity/homology between the polynucleotide of SEQ ID NO:2/polypeptide of SEQ ID NO:7 and the mouse polynucleotide/polypeptide indicated above, one cannot reasonably conclude that Applicant's asserted utility is substantial." Applicants respectfully disagree, and assert that the identity of about 33% and about 61% similarity in the catalytic domain of murine tyrosine phosphatase would allow one skilled in the art to reasonably conclude that the claimed invention was also a tyrosine phosphatase. Moreover, Applicants have disclosed that the claimed polynucleotides are expressed in breast cancer, and thus could be used for breast cancer diagnosis. Irrespective of the biological activity of the encoded polypeptide, Applicants contend that the assertion of this diagnostic utility, combined with expression in breast cancer, is sufficient to satisfy 35 U.S.C. § 101.

In view of the above, Applicants respectfully submit that the presently claimed invention possesses specific, substantial, credible, and well-established utilities which constitute patentable utilities under 35 U.S.C. § 101. Because Applicants' assertions of utility are sufficient to satisfy the requirements of 35 U.S.C. § 101, it is respectfully requested that the Examiner's rejection of the claims under 35 U.S.C. § 101 be reconsidered and withdrawn.

Further, the Federal Circuit and its predecessor determined that the utility requirement of 35 U.S.C. § 101 and the how to use requirement of 35 U.S.C. § 112, first paragraph, have the same basis, *i.e.*, the disclosure of a credible utility. *See In re Brana*, 51 F.3d 1560, 1564, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); *see also* M.P.E.P. § 2107(IV); Utility Examination Guidelines at 1098. As discussed above, the specification teaches specific and well-established utilities of the claimed invention, thereby enabling the skilled artisan to use the claimed polynucleotides. Since the specification teaches how to use the claimed polynucleotides with only routine experimentation and the specification describes specific and immediate utilities for the claimed invention, Applicants submit that the full scope of the claims is enabled. Accordingly, it is respectfully requested that the Examiner's rejection of the claims under 35 U.S.C. § 112, first paragraph, be reconsidered

II. Rejection of the Claims Under 35 U.S.C. § 112, First Paragraph

The Examiner has also rejected claims 33-42 under 35 U.S.C. § 112, first paragraph, asserting that there is no indication in the specification ass to public availabilty of the deposit. Paper No. 8, pages 8-9. In particular, the Examiner has required that Applicants provide assurances regarding viability and access to material deposited under terms of the Budapest Treaty.

In response, Applicants' representative hereby gives the following assurance by signature below:

Human Genome Sciences, Inc., the assignee of the present application, has deposited biological material under the terms of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure with the following International Depository Authority: American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Virginia 20110-2209 (present address). The deposit was made on March 3, 2000, accepted by the ATCC, tested and declared viable, and given ATCC Accession Number PTA1452. In accordance with M.P.E.P. § 2410.01 and 37 C.F.R. § 1.808,

assurance is hereby given that all restrictions on the availability to the public of ATCC Accession Number PTA1452 will be irrevocably removed upon the grant of a patent based on the instant application, except as permitted under 37 C.F.R. § 1.808(b). A partially redacted copy of the ATCC Deposit Receipt for Accession Number PTA1452 is enclosed herewith.

In light of the above, Applicants submit that the instant rejection under 35 U.S.C. § 112, first paragraph has been obviated, and should be reconsidered and withdrawn.

Conclusion

The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the allowance of this application. If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: September 26, 2003

Respectfully submitted,

By _____

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